510(k) Summary

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K133385

Date of Summary

January 3, 2014

510(k) Applicant

Broncus Medical, Inc.
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Device Overview

Trade Name:	LungPoint® ATV Planning and Navigation Software
Common Name:	Picture Archiving and Communications Systems
Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ

Predicate Device

The predicate devices for this premarket submission include:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System	Broncus Medical, Inc.*	#K112051, #K093423,
EP Navigator	Philips Medical	#K101311
*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.		

Device Description

The LungPoint Software is a software device, providing navigation guidance to help the physician plan and proceed to a predefined target site in the bronchial tree and surrounding soft lung tissue by providing a path, which is displayed on a 3D reconstruction of a CT scan. The LungPoint Software provides guidance to targets in the lung preselected by the physician. In doing so, the software provides guidance to lymph nodes or lesions to enable

tissue sampling. It can also facilitate the return to the location that had previously been treated for assessment or continued therapy, or to enable marker placement in soft lung tissue.

The software system consists of multiple modules that closely interact with each other to perform the overall product's functions. Each module is designed to perform a specific function such as airway tree segmentation, centerline calculation, etc and relies on outputs of other module(s) to perform its function. All modules share the same data structure defined in the Modules Interface section that is shared as binary and text files.

The software consists of two key programs: Planning and Procedure. The procedure program contains two separate procedural options, depending on the complexity and location of the lesion in the lung: (a) Virtual Bronchoscopic Navigation (VBN) and (b) Navigation with fluoroscopic guidance.

Intended Use / Indications for Use

The LungPoint software is intended to display images of the anatomy to aid the physician in guiding endoscopic tools or catheters during navigation through the same anatomy.

The LungPoint software is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract to a location in the tracheobronchial tree or lung tissue, and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not for pediatric use.

When under fluoroscopy guidance, the software enables users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with live fluoroscopy X-ray images of the same anatomy in order to support catheter/device navigation. The 3D segmented data set can be displayed with a color map annotation received from an external source.

The LungPoint tools (needle, balloon dilator, and sheath) are used with a bronchoscope, navigated by the LungPoint Software.

Technological Characteristics

The technological characteristics in the candidate LungPoint ATV Software are substantially equivalent to those in the predicate devices.

During guided navigation, the technology used is synchronization of virtual animation with the real bronchoscopic video via image matching. A fluoroscopic guidance module has been added to the previously cleared LungPoint VBN Software. This module overlays acquired and segmented 3D CT anatomical image data onto live fluoroscopic X-ray images of the same anatomy to enable fluoroscopic guidance of endoscopic accessories to the target.

Performance Data

Software verification and validation testing was performed to ensure that the LungPoint ATV Software successfully fulfilled the requirements defined in the Software Requirement Specifications (SRS). Each verification test protocol included detailed descriptions of dependencies, execution instructions, required input, expected output, and pass/fail criteria.

In addition, a preclinical study was performed in healthy canines to characterize the safety and performance of the LungPoint ATV Planning and Navigation Software in accessing implanted targets in soft lung tissue. The study demonstrated the LungPoint ATV software met its intended use for navigating and accessing target sites, with no safety issues observed.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing, the LungPoint ATV software performs as intended, and it was confirmed that no new questions of safety or effectiveness were identified during testing.

Comparison to Predicate Device

Design verification and validation testing confirmed that no new questions of safety or effectiveness were identified during testing, and that the LungPoint ATV Planning and Navigation Software performs as intended.

Fusing or superimposing selected 3D cross-sectional images of the targeted anatomy onto live 2D fluoroscopy images has been utilized in predicate devices cleared by FDA. Use of live fluoroscopy guidance makes the procedure as safe as the predicate, since the CT images are overlaid onto the live fluoroscopic images and multiple, user-definable image views are available to confirm the positioning of endoscopic tools or catheters and the navigation path during guided navigation. Use of live fluoroscopy guidance is a new feature for the LungPoint ATV software, but it is not new technology and it poses no new risks nor does it create different questions of safety and effectiveness.

Conclusion

The LungPoint ATV Planning and Navigation Software is substantially equivalent to the predicate devices cited, which have been cleared under the Federal Food, Drug, and Cosmetic Act, when considering each product's intended use, product code, principles of operation, and technological characteristics. The minor differences between the LungPoint ATV Software and the predicate devices raise no new issues of safety or effectiveness, and the LungPoint ATV Software is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Broncus Medical Inc.
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Consulting Director, Regulatory Affairs
1400 N. Shoreline Blvd., Bldg A, Suite 8
MOUNTAIN VIEW, CA 94043

Re: K133385
Trade/Device Name: Lungpoint ATV planning and navigation software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications Systems
Regulatory Class: Class II
Product Code: LLZ
Dated: January 24, 2014
Received: January 27, 2014

Dear Robin Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133385

Device Name
LungPoint ATV Planning and Navigation software

Indications for Use *(Describe)*

The LungPoint® ATV Planning and Navigation Software is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools and catheters in the pulmonary tract to a location in the tracheobronchial tree or lung tissue, and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not for pediatric use.

When under fluoroscopy guidance, the software enables users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with live fluoroscopy X-ray images of the same anatomy in order to support catheter/device navigation. The 3D segmented data set can be displayed with a color map annotation received from an external source.

The LungPoint tools (needle, balloon dilator, and sheath) are used with a bronchoscope, navigated by the LungPoint Software.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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